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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,365	12/13/2001	Bruce Robie	Implex-18	2786
28581	7590	12/29/2004	EXAMINER	
DUANE MORRIS LLP PO BOX 5203 PRINCETON, NJ 08543-5203			STOKES, CANDICE CAPRI	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/015,365	ROBIE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Candice C. Stokes	3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 07 September 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1,3,5-7,9-13,15-17,19-21,23,25-27,29-33,35-37 and 39-46 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3,5-7,9-13,15-17,19-21,23,25-27,29-33,35-37 and 39-46 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,3,10-13,20,21,23,30-33,40-41 and 45-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Hamada (USPN 6,436,101). With respect to Claims 1,10,11,20,21,30,31, and 40 Hamada discloses “an instrument for distracting a disc space between adjacent vertebrae and simultaneously preparing endplates of the vertebrae 451”. “Instrument 451” having “a body 455 having an upper surface 457” and lower surface 471”. Furthermore, “instrument 451” comprises “a first plurality of teeth 507 extending across the upper surface 457” and “a second plurality of teeth 521 extending across the lower surface 471” as best seen in FIG. 44. As to Claims 12 and 32, FIG. 37 shows the upper and lower surfaces 457,471 taper posteriorly such that the body has a thickness that decreases from the “anterior end 477” to the “posterior end 475”. With regards the Claims 3,13,23, and 33 as best shown in FIG. 35, “the instrument 451”, further comprises “an inserter 105” removably coupled to “the body 455”.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claims 9,19,29, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada. Hamada discloses the claimed invention except for the upper and lower surfaces of the instrument taper from the anterior end to the posterior end at an angle of about 7 degrees. It would have been obvious to one having ordinary skill in the art at the time of the invention to design the instrument such that it decreased at an angle of about 7 degrees from the anterior end to the posterior end, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

2) Claims 5-7,15-17,25-27,35-37 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada in view of Waldman (USPN 5,342,365). Hamada discloses the claimed invention with the exception of the first and second plurality of teeth including anterior wedges surfaces and posterior shovel surfaces. Regarding Claims 5,15,25, and 35 Waldman further teaches the plurality of teeth including arcuate root surfaces 26. As to Claims 6,16,26, and 36 wedge surfaces 38 and shovel surfaces 28 intersect to define cutting edges 42. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the wedge and shovel surfaces as taught by Waldman into the instrument disclosed

by Hamada in order to maintain the sharpness of the rasp and prevent build-up of excess tissue between the teeth of the rasp.

Regarding Claims 7,17,27, and 37, Hamada and Waldman teach the claimed invention except for the wedge and anterior surfaces angling back at the indicated angles. It would have been obvious to one having ordinary skill in the art at the time the invention was made to angle the surfaces back at 60 and 10 degrees relative to the imaginary line, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

*In re Boesch*, 617 F. 2d 272, 205 USPQ (CCPA 1980).

#### ***Response to Arguments***

Applicant's arguments filed 09/07/04 have been fully considered but they are not persuasive. Applicants submit that the disclosure provided by the Hamada patent of record does not teach or suggest an instrument or system comprising the presently recited structure of independent claims 1,11,21, and 31 and request that the rejection under U.S.C. 102 (e) be withdrawn. The Examiner asserts that the Hamada reference of record does meet the limitations of the independents claims as currently presented. Specifically to the amended portion of the independent claims, Hamada does teach a instrument with an upper and lower surface defining a body thickness that continuously decreases from anterior end to posterior end as shown in Fig. 17. The thickness of the body at the anterior end or at its maximum height is shown as being "SS". Therefore, Claims 1,3,5-7,9-13,15-17,19-21,23,25-27,29-33,35-37 and 39-40 remain rejected. Claims 41-46 are newly rejected.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Stokes whose telephone number is (571) 272-4714. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3732

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Candice C. Stokes

  
Cary E. O'Connor  
Primary Examiner